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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/723,720	11/26/2003	Nicholas Popadiuk	ETH-5113	9774
27777	7590	06/15/2007	EXAMINER	
PHILIP S. JOHNSON			POUS, NATALIE R	
JOHNSON & JOHNSON			ART UNIT	
ONE JOHNSON & JOHNSON PLAZA			PAPER NUMBER	
NEW BRUNSWICK, NJ 08933-7003			3731	
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			06/15/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Office Action Summary	Application No. 10/723,720	Applicant(s) POPADIUK ET AL.	
	Examiner Natalie Pous	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>5/12/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of species 1 in the reply filed on 3/26/07 is acknowledged. The traversal is on the ground(s) that the two species do not require separate structural configurations. This is not found persuasive because the term "encapsulated" indicates that the nonabsorbable material is covered on all sides by the absorbable material. This is not required by the separate layers as described in claim 1. Further, claim 9 indicates that the nonabsorbable material is porous, and thus the absorbable material encapsulating the nonabsorbable material is not only located on either side of nonabsorbable layer but also within it. This structural feature is not required by species 1 as described by claim 1.

Thus, the requirement is still deemed proper and is therefore made FINAL.

Claim Objections

Claim 7 is objected to because of the following informalities: line 2 recites "absorbable has a melting point." It is inferred that the correct wording is --absorbable material has a melting point--. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-4 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schilder (US 5686090) in view of Tormala et al. (US 6319264).

Schilder teaches a prosthetic repair device comprising a nonabsorbable material (33), a first absorbable material (32) having a first absorption rate, and a second absorbable material (31) having an absorption rate.

further comprising one or more additional nonabsorbable material (fig. 9).

further comprising one or more additional first or second absorbable material (fig. 9)

wherein the first absorbable material has a first side and a second side, and the nonabsorbable material has a first side and second side, where the second side of the nonabsorbable material is proximate to the first side of the first absorbable material and the second absorbable material is proximate to the second side of the first absorbable material (fig. 3).

wherein the first absorbable has a melting point that is lower than the melting points of the nonabsorbable material and the second absorbable material, wherein the first

absorbable material joins the nonabsorbable material to the second absorbable material (Column 4, proximate lines 27-37).

Schilder fails to explicitly teach wherein the second absorbable material has a faster absorption rate than the first absorption rate. Schilder does however teach wherein the different layers may have different degradation speeds. Tormala teaches a hernia mesh wherein the second layer has a faster absorption rate than the first absorption rate in order to induce scar tissue formation due to inflammatory reaction, and while the first absorbable material isolates the second absorbable material from the abdominal cavity, preventing tissue to tissue adhesion onto the intestines. It would have been obvious to one of ordinary skill in the art at the time the invention was made to disclose the second absorbable material as having a faster degradation rate than the first absorbable material to induce scar tissue formation due to inflammatory reaction, and while the first absorbable material isolates the second absorbable material from the abdominal cavity, preventing tissue to tissue adhesion onto the intestines.

Claims 5 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Schilder and Tormala as applied to claims 1 and 4 above, and further in view of Greenawalt et al. (US 2003/0100955). The combination of Schilder and Tormala teaches all limitations of preceding dependent claims 1 and 4 as previously described, and Schilder further teaches wherein the first absorbable material is a polydioxanone (Column 2, proximate lines 45-46), and wherein the nonabsorbable material is selected from the group consisting of polyolefins, polyesters, fluoropolymers, polyamides and combinations thereof (Column 2, proximate lines 49-50); however fails

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to teach wherein the nonabsorbable material is a polypropylene mesh and the second absorbable material is an oxidized regenerated cellulose fabric. Greenawalt teaches a biocompatible mesh for tissue repair comprising a bioabsorbable and a nonbioabsorbable layer, wherein the nonabsorbable material is a polypropylene mesh and the second absorbable material is an oxidized regenerated cellulose fabric since both of these materials are well known in the tissue repair art. It would thus have been an obvious matter of design choice to designate these materials since they are well known in the tissue repair art.

Claim 6 rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Schilder and Tormala as applied to claims 1 and 4 above, and further in view of Rousseau (US 6800082). The combination of Schilder and Tormala teaches all limitations of preceding dependent claims 1 and 4 as previously described, but fails to teach second sheet of the first absorbable material that is proximate to the first side of the nonabsorbable material. Rousseau teaches an absorbable mesh device comprising a nonabsorbable member and an absorbable member located on either side of the nonabsorbable member in order to stimulate tissue surrounding the defect on all sides. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Schilder and Tormala with a second sheet of the first absorbable material on the first side of the nonabsorbable material in order to stimulate tissue surrounding the defect on all sides of the device.

Conclusion


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie Pous whose telephone number is (571) 272-6140. The examiner can normally be reached on Monday-Friday 8:00am-5:30pm, off every 2nd Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tan-Uyen (Jackie) Ho can be reached on (571) 272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NRP
5/31/07


(JACKIE) TAN-UYEN HO.
PRIMARY EXAMINER

6/7/07